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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/781,296	01/13/97	HARLEY	J	OMRF161

18N2/1224

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EXAMINER	
PRIEBE,S	
ART UNIT	**PAPER NUMBER**
1819	9

DATE MAILED: 12/24/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 08/781,296	Applicant(s) Harley et al.
	Examiner Scott D. Priebe, Ph.D.	Group Art Unit 1819

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-26* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-26* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

It is noted that claims 1-5 and 11-18 encompass three distinct inventions as evidenced by claims 3 and 13, which recite a misjoined Markush group that includes compounds that do not share a common core structure and function.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 11-18, drawn to vaccine for Epstein-Barr viral autoimmune disorder comprising Epstein-Barr viral peptides, classified in class 424, subclass 186.1.

II. Claims 1-5, 11-18, drawn to vaccine for Epstein-Barr viral autoimmune disorder comprising Epstein-Barr viral nucleic acids, classified in class 514, subclass 44.

III. Claims 1-5, 11-18, drawn to vaccine for Epstein-Barr viral autoimmune disorder comprising Epstein-Barr viral carbohydrates, classified in class 514, subclass 23.

IV. Claim 6-10 and 19-22, drawn to diagnostic assay for detecting antibodies to Epstein-Barr virus, classified in class 435, subclass 7.1.

V. Claims 23-25, drawn to an *in vivo* screen for therapeutic compounds, classified in class 424, subclass 9.2.

VI. Claim 26, drawn to a screen for genetic markers, classified in class 435, subclass 5.

The inventions are distinct, each from the other because of the following reasons: Invention I-III and inventions IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the vaccines of inventions I-III can be used to vaccinate an individual against an immune disorder, as in the methods of inventions I-III, or in any of the methods of inventions IV-VI.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: The method of inventions I-III, IV, V, and VI each have different ultimate goals, e.g. therapeutic treatment, diagnostic assay for a virus, screen for therapeutic compounds and screen for genetic risk factors, require different products to carry out the methods, and comprise different method steps to reach the ultimate goal of the methods.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different distinct products, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Each of the vaccines of inventions I-III comprise chemically distinct active

ingredients, EBV peptides, nucleic acids and carbohydrates, which are structurally, biochemically, and functionally unrelated.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for each group is not required for any of the other groups, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed inventions I-III: the various diseases listed in claim 15.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5 and 11-17 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention IV: peptides with a sequence selected from one of SEQ ID NO: 1-3, 7, or 13-38.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6-8, 10 and 19-21 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Robert Hodges on 12/8/97 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Certain papers related to this application may be submitted to Art Unit 1819 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasemine Chambers, Ph.D., can be reached on (703) 308-2035.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe, Ph.D.
Examiner

December 22, 1997

Jasemine C. Chambers

JASEMINE C. C[illegible]
SUPERVISORY [illegible]
GROUP [illegible]